4. (Amended) The isolated nucleic acid molecule of Claim 3 wherein the mammal is a human.

5. (Amended) A method for diagnosing orofacial clefting in a patient, comprising detecting expression of a nucleic acid sequence shown in SEQ ID NO:1, or fragments or variants of the nucleic acid sequence shown in SEQ ID NO:1, in selected target tissues(s).

B1 cont

6. (Amended) A method for diagnosing orofacial clefting in patients suffering from, or suspected to be suffering from orofacial clefting, comprising detecting a mutation in a nucleic acid sequence shown in SEQ ID NO:1, or fragments or variants of the nucleic acid sequence shown in SEQ ID NO:1.

7. (Amended) A polypeptide or a protein comprising an epitope for an antibody, or a protein modified by one or more amino acid modifications and comprising an epitope, or a modified or unmodified fragment comprising an epitope for a tissue repair protein encoded by a nucleic acid sequence having at least 75% identity to a nucleic acid sequence shown in SEQ ID NO:39.

B2

8. (Twice Amended) A delivery vehicle comprising the nucleic acid molecule of Claim 1 and/or the polypeptide of Claim 7, which is in the form of a suspension.

9. (Amended) The delivery vehicle of Claim 8, wherein the delivery vehicle is adapted to deliver the nucleic acid molecule or polypeptide to a selected tissue.

B3

10. (Amended) An antibody raised against the polypeptide of Claim 7.

11. (Amended) The antibody of Claim 10 wherein the antibody is a monoclonal antibody.

12. (Amended) A method for diagnosing orofacial clefting, comprising detecting expression of a protein recognized by the antibody of claim 10.

13. (Amended) A method for detecting the antibody of claim 10 in a sample, comprising:

B3 cont.

labeling a ligand comprising a protein or protein fragment of SEQ ID NO:2 present in the sample;

contacting the sample with the antibody of claim 10, wherein the antibody is immobilised which results in binding of the immobilised antibody to the labelled ligand; and

detecting the labelled ligand bound to the immobilised antibody in the sample.

14. (Twice Amended) A method for the treatment of orofacial clefting, comprising administering to a patient suffering from orofacial clefting the nucleic acid molecule of Claim 1 and/or polypeptide of Claim 7.

B4

15. (Twice Amended) A method for treating wounds and/or promoting tissue repair, comprising administering to a patient suffering from a wound and/or tissue damage the nucleic acid molecule of Claim 1 and/or the polypeptide of Claim 7.

16. (Twice Amended) A method of treating wounds and/or promoting tissue repair, comprising administering to a patient suffering from a wound and/or tissue damage a composition comprising the delivery vehicle of Claim 8.

17. (Twice Amended) A pharmaceutical composition comprising the nucleic acid of Claim 1 and/or the protein of Claim 7.

18. (Twice Amended) A method for treating orofacial clefting and/or wound healing and/or tissue repair comprising administering to a patient the nucleic acid of Claim 1 and/or the protein of Claim 7.

B5

19. (Amended) An isolated nucleic acid molecule encoding a tissue repair protein comprising a nucleotide sequence which hybridises to a nucleic acid sequence shown in SEQ ID NO:3 under high stringency conditions.

20. (Amended) The isolated nucleic acid of Claim 19 wherein the stringent conditions are 1 x SSC, 0.1% SDS at 65°C.

B6

21. (Twice Amended) The isolated nucleic acid of Claim 19 wherein the nucleic acid molecule is from a mouse.

B7

22. (Amended) The polypeptide or a protein of claim 7, wherein the nucleic acid sequence comprising at least 75% identity to the nucleic acid sequence shown in SEQ ID NO:39 comprises a nucleic acid sequence shown in SEQ ID NO:3, or a fragment thereof.

B8

23. (Twice Amended) A delivery vehicle comprising the isolated nucleic acid molecule of Claim 20 and/or the polypeptide of Claim 22.

24. (Amended) An antibody raised against the polypeptide of Claim 22.

25. (Amended) The antibody of Claim 24 wherein the antibody is a monoclonal antibody.

26. (Twice Amended) A method for diagnosing or detecting orofacial clefting comprising detecting expression of a protein recognized by the antibody of claim 24.

B9

27. (Amended) A method of producing a transgenic mammal comprising disrupting a gene, or the effective part of the gene, wherein the gene encodes at least one tissue repair protein, and a resulting phenotype is a cleft palate in the transgenic mammal.

28. (Amended) The method of Claim 27 wherein the transgenic mammal is a rodent.

29. (Twice Amended) The method of Claim 28 wherein the rodent is a mouse.

30. (Twice Amended) The method of Claim 27 wherein the gene encoding the tissue repair protein is a nucleic acid molecule comprising a nucleotide sequence which hybridizes to a nucleic acid sequence shown in SEQ ID NO: 3 under high stringency conditions.

31. (Amended) The method of Claim 27 wherein the transgenic mammal is a human.

B9 cont.

32. (Twice Amended) The method of Claim 27 wherein the gene encoding the tissue repair protein is a nucleic acid molecule which encodes a tissue repair protein and comprises a nucleotide sequence which hybridizes to a nucleic acid sequence shown in SEQ ID NO: 1 under high stringency conditions.

33. (Amended) A reporter gene construct based on a promoter region of a gene, or an effective part thereof encoded by SEQ ID NO:1, or a fragment or variant thereof.

34. (Amended) A method for detection/screening a pharmaceutical and/or other compound, comprising:

contacting the pharmaceutical and/or other compound with a reporter gene construct of claim 33; and

determining a transcriptional response of the reporter gene to the pharmaceutical or other compound wherein the transcriptional response is an indicator of a potential teratogenic effect of the pharmaceutical or other compound.

35. (Reiterated) A cloned nucleic acid molecule encoding a tissue repair protein contained in a Yeast Artificial Chromosome species designated as AB 1380 YAC-CP 1 and deposited with NCIMB Limited of Aberdeen, Scotland (UK) under accession number NCIMB 41005.

B10

36. (Amended) An isolated nucleic acid encoding a tissue repair protein, the nucleic acid selected from the group consisting of:

(a) DNA comprising a nucleotide sequence shown in SEQ ID NO:39;

(b) nucleic acids which hybridize to DNA of (a) above under stringent conditions; and

(c) nucleic acids which differ from the DNA of (a) or (b) above due to the degeneracy of the genetic code, and which encode a tissue repair protein encoded by the DNA of (a) or (b) above.

37. (Amended) An isolated nucleic acid encoding a tissue repair protein, selected from the group consisting of:

(a) DNA comprising a nucleotide sequence shown in SEQ ID NO:3;

(b) nucleic acids which hybridize to DNA of (a) above under stringent conditions; and

(c) nucleic acids which differ from the DNA of (a) or (b) above due to the degeneracy of the genetic code, and which encode a tissue repair protein encoded by the DNA of (a) or (b) above.

Please add the following new claims:

38. (New) The isolated nucleic acid molecule of claim 1, wherein the nucleic acid comprises at least 75% identity to a nucleic acid sequence shown in SEQ ID NO:39.

39. (New) The isolated nucleic acid molecule of claim 38, wherein the nucleic acid comprises at least 85% identity to a nucleic acid sequence shown in SEQ ID NO:39.

40. (New) The isolated nucleic acid molecule of claim 38, wherein the nucleic acid comprises at least 95% identity to a nucleic acid sequence shown in SEQ ID NO:39.

41. (New) The polypeptide or protein of claim 7, wherein the nucleic acid sequence encodes a protein comprising an amino acid sequence shown in SEQ ID NO:2.

42. (New) The polypeptide or protein of claim 22, wherein the nucleic acid sequence encodes a protein comprising an amino acid sequence shown in SEQ ID NO:4.